4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

2013 Parenteral Drug Association/Food and Drug Administration Joint Regulatory Conference: Driving Quality and Compliance Throughout the Product Life Cycle in a Global Regulatory Environment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA), in co-sponsorship with the Parenteral Drug Association (PDA), is announcing a public conference titled "Driving Quality and Compliance Throughout the Product Life Cycle in a Global Regulatory Environment." The conference will cover current issues affecting the industry as well as explore strategies and approaches for ensuring conformance with regulations to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

Date and Time: The public conference will be held on September 16, 2013, from 7 a.m. to 6 p.m.; September 17, 2013, from 7:30 a.m. to 6:15 p.m.; and September 18, 2013, from 7:30 a.m. to 12:15 p.m.

Location: The public conference will be held at the Renaissance Washington Hotel, 999 9th St., NW., Washington, DC 20001, 202-898-9000, FAX: 202-289-0947.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301-656-5900, ext. 111, FAX: 301-986-1093, email: info@pda.org or Ken Nolan, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5314, Silver Spring, MD 20993, 301-796-8629, email: kenneth.nolan@fda.hhs.gov.

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Renaissance Washington Hotel at the reduced conference rate, contact the Renaissance Washington Hotel (see Location)--cite the meeting code "PDA." Room rates are: Single or Double: $299, plus 14.5 percent State and local taxes. Reservations can be made on a space and rate availability basis.

Registration: Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis on each day of the public conference beginning at 7 a.m. on September 16, 2013. The cost of registration is as follows:

Cost of Registration		
Affiliation	Through August 6, 2013	After August 6, 2013
Member	$1,895	$2,095
Nonmember	$2,144	$2,344
Government/Health Authority	$700	$700

Cost of Registration		
Affiliation	Through August 6, 2013	After August 6, 2013
Member		
Government/Health Authority Nonmember*	$800	$800
Academic Member	$700	$700
Academic Nonmember*	$800	$800
Student Member	$280	$280
Student Nonmember*	$310	$310

*Applicable Nonmember rates

Please visit PDA's Web site at http://www.pda.org/pdafda2013 to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

If you need special accommodations due to a disability, please contact Wanda Neal (see Contact), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to "PDA." Mail your registration information along with your payment to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., suite 200, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site at http://www.pda.org/pdafda2013.

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see Contact).

Transcripts: Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information request.

Written requests are to be sent to Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from some of today's leading pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Regulatory Submission and Meetings
- Quality Risk Management Implementation
- Manufacturing in the Future
- Quality Systems
- Regulatory Considerations During Development
- Cell Therapy Innovations
- Life Cycle Management
- Process Validation
- Validation FDA Guidance
- Challenges of Contract Manufacturing Organizations
- Contract Agreements
- Drug Safety

- Emerging Active Pharmaceutical Ingredients (API) Regulations
- Investigations
- Emerging API Regulations
- User Fees
- Excipient Best Practices
- Good Manufacturing Practices Foreign Inspections Findings
- Regulatory Process to Approval (Inspectional Readiness)
- Combination Products and Companion Diagnostics

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government Agencies to small businesses.

Dated: April 1, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

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